

#### REMARKS

Claims 1-42 have been canceled. Claims 43-52 remain pending in the present application. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

#### *Claim Objections*

The Office Action objected to claim 47 as reciting non-elected subject matter, indicating that the claim should be restricted to the elected species which includes the estrogen receptor and estradiol. In its response to the Office Action requiring a restriction, applicant was required to elect a single disclosed combination of species for prosecution on the merits from each of (1), (2) and (3) on page 3 of Paper Number 5. Applicant elected PNRC as the co-regulatory protein, the estrogen receptor, and estradiol. (*See* Response to Restriction Requirement, page 1, filed 8 December 2000). Even so, the Office Action stated that upon the allowance of a generic claim, the applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim. (*See* Paper Number 5, page 4). Because the Office Action stated claims 1-52 are generic, it is respectfully submitted that all of the listed species should be examined.

#### *Claim Rejections - 35 U.S.C. § 112, First Paragraph*

Claims 43-52 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. More specifically, the Office Action rejected claims 43 and 52 as directed to all possible chemicals which promote the binding of the claimed co-regulatory protein and nuclear receptor or nuclear receptor ligand binding domain, stating that the specification only provides representative species of hormones or ligands encompassed by these claims. Furthermore, the Office Action asserted no disclosure of any particular structure to

function/activity relationship in the disclosed species and no additional representative species are disclosed. It is submitted claims 43 and 52 are drawn to *a method of screening for a protein which interacts with a chemical* (emphasis added), rather than drawn to chemical compounds. The purpose of the present invention is to screen for proteins which in turn, interact with chemicals, and one in the art clearly can screen any desired chemical. The specification enables one of ordinary skill in the art to perform each step of claims 43 and 52; therefore, applicant respectfully requests reconsideration of the rejection.

The Office Action rejected claims 43, 45 and 52 as directed to all possible proteins comprising an amino acid sequence set forth in SEQ ID NO: 5 or SEQ ID NO: 9, and the specification allegedly provides only for a single representative species of protein comprising the claimed amino acid sequences: a protein consisting of an amino acid sequence as set forth in SEQ ID NO: 8. Furthermore, the Office Action asserted there is no disclosure of any particular structure to function/activity relationship in the disclosed species, and the specification failed to describe additional representative species of these proteins other than a protein having SEQ ID NO: 5 or SEQ ID NO: 9. Applicants respectfully disagree. Please note page 8 of the specification, lines 6-9, where the interaction between PNRC and the nuclear receptors is dependent on an S-D-P-P-S-P-S (SEQ ID NO: 5) core ligand motif for SH3 in a stretch of proline-rich sequence at its carboxy-terminus (SEQ ID NO: 9). Unlike most of the coactivators, this SDPPSPS region where interaction occurs is sufficient. In the present invention, claims 43, 45, and 52 are directed to a method of screening for a protein wherein the method includes cotransfecting cells with a co-regulatory protein comprising the SDPPSPS sequence. It is submitted that any protein may be tested with ligands known to interact with the protein of SEQ ID NO:8 or with SEQ ID NO:5 to determine if such a protein will be usable in the claimed method.

Finally, claims 43-52 were rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a protein having an amino acid sequence consisting of

SEQ ID NO:8 and the hormone or ligand selected from the group consisting of estradiol, dexoycortosterone, progesterone, and retinoic acid; does not reasonably provide enablement for any chemical or any protein comprising an amino acid sequence set forth in SEQ ID NO:5 or SEQ ID NO: 9. An enablement inquiry focuses on what the skilled artisan would understand, and the specification need not teach, and preferably omits what is well known in the art. A specification complies with the enablement requirement, even if it requires the skilled artisan to engage in a "reasonable" amount of routine experimentation, so long as such experimentation is not "undue." Sufficient disclosure exists through illustrative examples and terminology to teach those of ordinary skill in the art how to make and how to use the invention as broadly as it is claimed. A search for the biological function, biological activity, or utility of said protein or the specific chemical which promotes the binding of the claimed co-regulatory protein, the Office Action argued as outside the realm of routine experimentation. Applicants assert it is not necessary to search for the functions or activity of these compounds since the claims are drawn to methods, not to compounds. The claims are drawn to methods of screening and applicants urge that the disclosure fully enables one of skill in the art to practice the claimed methods.

*Claim Rejections - 35 U.S.C. § 112, Second Paragraph*

Claims 43-52 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, because the nature of the interaction claimed in claims 43 and 52 between the claimed protein and chemical is not known and has not been defined. It is submitted the claims define what interaction takes place, i.e., an interaction occurs when an enhanced signal occurs. Furthermore, the Examiner asserted the claims recite a chemical which has not been specifically defined. The object of the present invention is to screen chemicals for activity, so it is not necessary to specify a chemical. Finally, the Examiner stated claim 47 is indefinite because the

acronym ER is not defined in the claim. Claim 47 has been amended and should now overcome the rejection.

### CONCLUSION

Favorable action on the merits is respectfully requested. In the event there are any issues which can be expedited by telephone conference, the Examiner is cordially invited to call the undersigned at the number indicated below.

RESPECTFULLY SUBMITTED,					
NAME AND REG. NUMBER	Stephen A. Saxe, Reg. No. 38,609				
SIGNATURE	<i>Stephen A. Saxe</i>			DATE	<i>May 29, 2001</i>
Address	Rothwell, Figg, Ernst & Manbeck Suite 701-East, 555 13th Street, N.W.				
City	Washington	State	D.C.	Zip Code	20004
Country	U.S.A.	Telephone	202-783-6040	Fax	202-783-6031

**Attachments:** Marked-Up Copy of Amended Claim 47

**Amended Claim 47: Version with markings to show changes made**

47. (*Amended*) The method of claim 43 wherein said nuclear receptor ligand binding domain and said ligand or hormone are selected from the sets of (i) ER estrogen receptor and estradiol, (ii) GR glucocorticoid receptor and deoxycorticosterone, (iii) AR androgen receptor and dihydrotestosterone, (iv) PR progesterone receptor and progesterone, (v) TR thyroid hormone receptor and T3, (vi) RAR retinoic acid receptor and all-*trans*-retinoic acid, and (vii) RXR 9-*cis*-retinoic acid receptor and 9-*cis*-retinoic acid.